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REMARKS

The action by the Examiner of this application, together with the cited references, have been given careful consideration. Following such consideration, claims 1, 3, 8-14 have been amended to more clearly define the patentable invention applicant believes is disclosed herein. Moreover, claims 4-7 have been canceled, and claim 2 is unchanged by the present amendment paper. Furthermore, amendments have been made to the specification at paragraphs beginning at page 8, line 13; page 9, line 1; page 9, line 12 and page 10, line 29. It is respectfully submitted that no new matter has been introduced by the amendments to the specification. This amendment is presented according to "Revised Amendment Practice" (37 C.F.R. 1.121), effective July 30, 2003. It is respectfully requested the Examiner reconsider the claims in their present form, together with the following comments, and allow the application.

The Examiner has objected to the drawings under 37 CFR 1.83(a). In particular, the Examiner notes that the "endotracheal tube" and the "flexible diaphragm, pneumatic pressure sensing valves, the rotation flow meter propellers and electrical gas flow sensors" must be shown or canceled from the claims. In view of the Examiner's comments, a replacement FIG. 1 is submitted herewith for consideration by the Examiner. FIG. 1 has been amended to show an endotracheal tube 34. The other features objected to by the Examiner have been cancelled from the claims. One skilled in the art (i.e.: doctors, nurses or emergency medical personnel) would recognize that a standard bag valve mask as illustrated in FIG. 1 is commonly used in association with an endotracheal tube in the event that the patient has some obstruction or blockage to their airway, such as caused by inflammation, physical injury or trauma of some type. Bag valve masks are commonly used in association with a common tubular fitting that fits a face mask or an endotracheal tube interchangeably. As such, therefore, the amendment to FIG. 1, and a corresponding amendment to the specification at the paragraphs beginning at page 8, line 13 and at page 10, line 29, do not constitute new matter, but are implicit in the original specification. In view of the foregoing, it is respectfully requested that the Examiner withdraw the objection to the drawings.

The Examiner has objected to the specification because the Examiner believes that 112, sixth paragraph has been invoked by the claim language, and it is unclear what impliedly disclosed structures are required to the means-plus-function recitation. It is

respectfully submitted that this Examiner's objection to the specification has been addressed through the present amendment to the claims. Accordingly, it is respectfully requested that that the objection to the specification be withdrawn.

The Examiner has objected to claims 1-14 for a variety of minor informalities. The Examiner's comments have been carefully considered, and appropriate amendments have been made to the claims to address the Examiner's objections. Specifically, the Examiner's objection to claims 3, and 8-14 have been addressed as suggested by the Examiner. Furthermore, the claims have been reviewed to provide the necessary antecedents and use "a" and "the" when appropriate. It is respectfully requested that the objections to claims 1-14 be withdrawn in view of the present amendment.

The Examiner has rejected claims 1-14 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Appropriate corrections have been made by amendment. Specifically, the Examiner's objection to the antecedent basis for claim 1 has been addressed by reciting "a patient airway." It is respectfully requested that the Examiner now withdraw the 35 U.S.C. 112, second paragraph rejection.

The Examiner has indicated that claims 8-14 recite **patentable subject matter**, and would be allowable if rewritten to overcome the objections and rejections under 35 U.S.C. 112, second paragraph, and to include all of the limitations of the base claim and any intervening claims. However, the Examiner has rejected claims 1, 2 and 4-7 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,537,998 to Bauman, and has rejected claim 3 as being obvious in view of the combined teachings of U.S. Patent No. 5,537,998 to Bauman and U.S. Patent No. 3,009,459 to Ruben. It is respectfully submitted that neither Bauman nor Reuben, taken individually or in combination, teach or suggest the applicant's invention as presently set forth in claim 1.

U.S. 3,009,459 to Ruben shows a conventional "bag valve mask" with an airbag 1 that is manually squeezed to pump air from the one way air inlet valve 4 to the one way outlet valve 5 and provide compressed air to the breathing mask 11. This patent merely shows the conventional bag 1 with mask 11 and necessary one way valves 4 and 5 which are conventional in the prior art.

U.S. 4,821,713 to Bauman includes a slight variation on the bag valve mask where the air receptacle 10 is a simple bellows with a single discharge outlet 11 that serves to intake and output air through a single outlet 11 into the tubular section 16. One way inlet flap valve 31 intakes air and oxygen through opening 26 into the air receptacle 10. Compression of the air receptacle 1 raises the gas pressure such that the one way intake flap valve 31 closes and one way outlet flap valve 32 opens to deliver compressed gas to the mask 20. Therefore, the structure shown by Bauman is functionally equivalent to the bag valve mask of Ruben with the one way inlet and outlet valves removed from the compressible bag itself and placed on the tubular delivery device.

It is respectfully submitted that U.S. 4,821,713 to Bauman, alone or together with U.S. 3,009,459 to Ruben, do not disclose a flow (i.e., fluid volume/time) control valve having a plug with a gas flow impingement surface such that the plug is normally biased away from the valve seat and urged towards the valve seat by gas flow impinging against the gas flow impingement surface, as defined by claim 1.

In contrast, U.S. 4,821,713 to Bauman merely provides different means to visually indicate the pressure of gas delivered to the patient and in the case of excess pressure being delivered provides for two types of pressure relief valves as described in detail below. Referring to FIG. 6, a safety valve 60 is biased to a closed position with spring 61 and in the event of excess pressure, the spring 61 is compressed and excess gas is vented to the atmosphere. Alternatively, referring to FIGS. 10 and 11, an air bleed 120 is used to control the pressure of air passing to the mask by manually adjusting a rotatable cap 121 to expose various vent openings 125 to 127 to exhaust excessive gas pressure through vent 123 in the wall 124.

Bauman provides a visual indicator of the pressure delivered by pressure indicator balloon 50 in FIGS. 1 and 3 which in conjunction with slider 52 and indicia 120 provides a visual indication of pressure. FIGS. 6 and 7 show an alternative indicator plunger 56 in bore 57 which slides outwardly to indicate air pressure against the biasing force of spring 59. FIGS. 12 and 13 show similar sliding mechanisms to indicate the built up pressure inside the mask.

In no case, therefore, do the cited references teach or suggest use of a flow volume control valve, but merely teach pressure relief valves which exhaust excess pressure to the atmosphere.

The present invention discloses a flow control valve with a valve seat and a valve plug to define a flow control orifice. The valve plug has a gas flow impingement surface and a valve seat mating surface. The plug is normally biased away from the valve seat, by a spring in the embodiment illustrated. The plug is urged towards the valve seat to restrict the flow control orifice, by the force exerted by gas flowing and impinging against the gas flow impingement surface.

A health care provider or user who manually squeezes the air receptacle 10 of Bauman will notice the visual indicators showing excess pressure and may hear the flow of excess gas escaping from the pressure relief valve 60 or through the vent openings 125 to 127.

In contrast, the present invention provides a physical resistance to the manual squeezing of the bag valve mask device 1, as a tactile feedback. The prior art provides only visual feedback or auditory feedback to the user. The user of the invention is therefore trained by this tactile feedback to limit the physical force applied to squeeze the bag 3 by the resistance to flow and resultant backpressure in the bag created by the flow control valve restricting air flow. Resistance to flow caused by the flow control valve creates a back pressure and the back pressure translates into a firm resisting bag 3 which serves as a tactile feedback message to warn the user that excessive physical force is being applied to the bag 3.

As mentioned in the background of the art, over pressure caused by excessive squeezing of the bag can lead to gastric distension and aspiration of the stomach contents which can cause the patient to choke on their own vomit and result in medical complications even leading to death.

While U.S. 4,821,713 to Bauman addresses this danger by providing excess pressure venting, auditory and visual indication of excess pressure, such as pressure relief valve 60 and/or manually adjustable air vent structure 120, these do not suggest the solution taught by the invention.

The invention provides a flow control valve which prevents the delivery of excessive air flow to the patient, rather than just warning of this condition and venting excess pressure after it has been delivered. Further the invention creates a back pressure in the bag to eventually teach the user to restrain themselves and not apply excessive pressure to the bag.

In summary, claim 1 has been amended to distinguish over the prior art on the basis of the flow control valve, that prevents the over-pressure condition from arising. The prior art merely shows pressure relief valves which exhaust excess pressure to the atmosphere after the fact and do not prevent the creation of excess pressure in the first place.

The remaining pending claims depend from claim 1, thus it is respectfully submitted that these claims are patentable over the prior art for at least the reasons set forth above in connection with claim 1.

The prior art made of record and not relied upon has also been reviewed. It is respectfully submitted that none of these additional references teach or suggest the applicants' invention as defined by the present claims.

In view of the foregoing, it is respectfully submitted that the present application is now in proper condition for allowance. If the Examiner believes there are any further matters which need to be discussed in order to expedite the prosecution of the present application, the Examiner is invited to contact the undersigned.

If there are any fees necessitated by the foregoing communication, please charge such fees to our Deposit Account No. 50-0537, referencing our Docket No. SW7255US.

Respectfully submitted,

Date: July 21, 2003

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